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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/557,745

11/21/2005

Fumihiro Hayashi

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EXAMINER

VO, HAI

ART UNIT

PAPER NUMBER

1794

MAIL DATE

DELIVERY MODE

10/02/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/557,745	Applicant(s) HAYASHI, FUMIHIRO	
	Examiner Hai Vo	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/11/2006 and 11/21/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Steinhaus et al (US 6,546,292). Steinhaus discloses an implantable electrode comprising a cell ingrowth layer 40, and a cell exclusion layer 38 as shown in figures 2A and 3. The cell ingrowth layer is made from a porous ePTFE having an average pore size greater than 3 microns (column 8, lines 25-35). The cell exclusion layer 38 is formed from ePTFE having an average pore size ranging from 0.05 to 0.4 microns (column 7, lines 30-35). It is contemplated that the cell exclusion layer 39 has the portions surrounding aperture 53 densified to become non-porous (column 8, lines 1-5 and figure 3A). Likewise, the cell ingrowth layer and the cell exclusion layer have different pore size and porosity. As the bubble point is

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regulated by the pore size and porosity, it is the examiner's position that the cell ingrowth and the cell exclusion layers would inherently have different bubble points. Accordingly, Steinhaus anticipates or strongly suggests the claimed subject matter.

4. Claims 1-4, 10-14, 16 and 17 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Saxon (US 5,725,577). Saxon discloses a prosthesis comprising a first portion and a second portion substantially surrounding the first portion as shown in figures 7 and 8. The first portion has vital tissue-blocking ability (column 5, lines 1-10). The second portion has vital tissue—penetrating ability (column 6, lines 32-37). Saxon does not specifically disclose the pore size of the first portion. However, it appears that the ePTFE has a surface that does not facilitate as substantial a fibroblastic reaction in the host tissue, therefore, it is the examiner's position that the ePTFE would inherently have a pore size within the claimed range so as not to be susceptible to tissue infiltration. Schuldt-Hempe et al (US 2004/0034373) is relied on as evidence to show a state of fact, that is, the second portion of polypropylene mesh which is commercially available under the trade name MARLEX® has a pore size of 0.8 mm which is within the claimed range (table 4 of Schuldt-Hempe). Saxon discloses the prosthesis comprising two first portions with a second portion position therebetween (column 6, lines 5-10). The second portion surrounding the first portion (column 5, lines 65-67). Likewise, it is contemplated that the three-layer laminate comprising a second portion

sandwiched between the two first portions wherein the second portion is exposed through the openings of the first portions so as to allow sufficient tissue ingrowth. Accordingly, Saxon anticipates or strongly suggests the claimed subject matter.

5. Claims 5-9, 15, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saxon (US 5,725,577) as applied to claim 1 above, and further in view of Steinhaus et al (US 6,546,292). Saxon does not specifically disclose the cell ingrowth portion formed from an ePTFE. Steinhaus, however, teaches an implantable device comprising a cell ingrowth layer 40, and a cell exclusion layer 38 as shown in figures 2A and 3. The cell ingrowth layer is made from a porous ePTFE having an average pore size greater than 50 microns (column 8, lines 25-35). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the ePTFE with an average pore of 50 microns or greater for the cell ingrowth portion because ePTFE and polypropylene mesh have been shown in the art to be recognized equivalent materials with microstructure designed to promote cellular penetration into the materials. The resulting prosthesis would have the cell ingrowth portion having the pore size and porosity different from the cell exclusion portion. As the bubble point is regulated by the pore size and porosity, it is the examiner's position that the two portions would inherently have different bubble points.
6. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saxon (US 5,725,577) as applied to claim 1 above, and further in view of Amid et al (US 2003/0187516). Saxon does not specifically disclose the cell ingrowth portion

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and the cell exclusion portion having different color. Amid, however, teaches an implantable prosthesis comprising a cell ingrowth portion 24, and a cell exclusion portion 26 (paragraphs 29, 32, figure 1). Amid discloses the cell exclusion portion includes a plurality of preformed indicia with a contrasting color ink or dye (paragraph 57). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide one or more indicia on the cell exclusion portion of the prosthesis motivated with the desire to aid the surgeon in attaching the prosthesis at preferred anchoring location.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hai Vo whose telephone number is (571) 272-1485. The examiner can normally be reached on Monday through Thursday, from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on (571) 272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hai Vo/
Primary Examiner, Art Unit 1794